AMENDMENTS TO THE SPECIFICATION:

Page 1, after the title, please insert as follows:

This application is the U.S. national phase of international application **PCT/IB2004/002245** filed **9 July 2004**, which designated the U.S. and claims priority to **IT MO2003A000201** filed **11 July 2003**, the entire contents of each of which are hereby incorporated by reference.

Please amend the paragraph beginning at page 2 line 4, as follows:

According to a first aspect of the present invention a system is provided for the infusion of pharmacological solutions comprising a containing ~~means~~ arrangement suitable for containing a pharmacological solution, a pumping ~~means~~ device for generating a flow of said pharmacological solution from said containing ~~means~~ arrangement, ~~characterised in that~~ wherein it furthermore comprises an adjusting ~~means~~ device, to vary said flow and a command and control ~~means~~ device operationally associated with said adjusting ~~means~~ device.

Please amend the paragraph beginning at page 2 line 12, as follows:

Owing to the command and control ~~means~~ device associated with the adjusting ~~means~~ device it is possible to programme the trend over time of the flow of pharmacological solution according to preset curves, obtained for example on the basis of the patient's circadian rhythms.

Please amend the paragraph beginning at page 2 line 17, as follows:

In an advantageous embodiment of the present invention said adjusting ~~means~~ device comprises at least one solenoid valve.

Please amend the paragraph beginning at page 2 line 23, as follows:

The use of a valve of the normally closed type has the advantage of immediately interrupting the delivery of the pharmacological solution if a fault occurs in the command and control ~~means~~ device, for example an interruption to the electricity supply.

Please amend the paragraph beginning at page 2 line 28, as follows:

According to a further advantageous embodiment of the present invention, said command and control ~~means~~ device commands a pulsed actuation of said solenoid valve, said flow being determined by the number of actuations of the solenoid valve in the time unit.

Please amend the paragraph beginning at page 3 line 13, as follows:

According to a further advantageous embodiment of the present invention, said pumping ~~means~~ device comprises an elastomeric container wherein said pharmacological solution is inserted.

Please amend the paragraph beginning at page 3 line 24, as follows:

In a further advantageous embodiment of the present invention, said command and control ~~means~~ device is operationally associated with a plurality of solenoid valves, each one of which is associated with a different infusion circuit.

Please amend the paragraph beginning at page 4 line 1, as follows:

In a further advantageous embodiment of the present invention, said command and control ~~means~~ device comprises an interface ~~means~~ element for connecting the command and control ~~means~~ device with a data processing ~~means~~ system.

Please amend the paragraph beginning at page 4 line 13, as follows:

According to a further aspect of the present invention a method is provided for the infusion of a pharmacological solution in a patient comprising generating a flow of said pharmacological solution from a container containing said pharmacological solution, sending said flow to a catheter ~~means~~ inserted in the body of said patient, adjusting said flow by an adjusting ~~means~~ device, ~~characterised in that~~ wherein it furthermore comprises programming said flow and infusion times by means of a programming ~~means~~ device acting on said adjusting ~~means~~ device.

Please amend the paragraph beginning at page 5 line 3, as follows:

With reference to Figure 1, the system according to the invention comprises a pumping ~~means~~ device 1, ~~consisting of~~ comprising an elastomeric container 3, fixed to a support 4 provided with fixing and closing ~~means~~ elements 7, and inserted into a containing and protection element 2 suitable for housing the elastomeric container 3 when the latter dilates through the effect of the introduction of the pharmacological solution and for protecting it from accidental damage.

Please amend the paragraph beginning at page 5 line 17, as follows:

The protecting element 2 comprises an inlet ~~means~~ portion 9 for introducing a pharmacological solution into the elastomeric container 3. The inlet ~~means~~ portion 9 is provided with a check valve (not shown) to prevent pharmacological solution introduced into the elastomeric container 3 possibly flowing back through the inlet ~~means~~ portion 9 through the effect of the pressure exerted thereupon by the walls of the elastomeric container 3. The inlet ~~means~~ portion 9 is furthermore provided with a connecting ~~means~~ element 11, for example a connecting ~~means~~ element of the "luer-lock" type, that can be coupled with a delivery ~~means~~ device such as for example a syringe to introduce the pharmacological solution to the elastomeric container 3. The inlet ~~means~~ portion 9 may be equipped with a closing ~~means~~ element 8, for example a plug, that can be removed only when the pharmacological solution has to be introduced into the elastomeric container 3.

Please amend the paragraph beginning at page 5 line 32, as follows:

The protecting element 2 furthermore comprises an outlet ~~means~~ portion 10 through which the pharmacological solution introduced into the elastomeric container 3 can flow out thereof through the effect of the pressure exerted thereupon by the walls of the container 3.

Please amend the paragraph beginning at page 6 line 3, as follows:

The outlet ~~means~~ portion 10 can be connected to ~~an~~ a first end of a fitting ~~means~~ element 12, for example a joint pipe, ~~the opposite~~ a second end of which is connected to a valve arrangement ~~means~~ 13, the function of which is to adjust the flow of

pharmacological solution exiting the elastomeric container 3.

Please amend the paragraph beginning at page 6 line 8, as follows:

The valve arrangement ~~means~~ 13 may comprise a solenoid valve of the normally closed type.

Please amend the paragraph beginning at page 6 line 22, as follows:

The valve 13 is piloted by a piloting ~~means~~ device 19, connected electrically, by means of an electrical connection 16 to the solenoid of the valve 13.

Please amend the paragraph beginning at page 6 line 25, as follows:

The piloting ~~means~~ device 19 comprises a microprocessor to pilot the valve 13, that sends sequences of pulses to the solenoid of the valve that cause corresponding opening and closing of the valve. The flow of pharmacological solution that passes through the valve 13 and is sent to the catheter inserted into the body of the patient is proportional to the number of openings and reclosings of the valve 13 in the time unit, i.e. to the number of pulses in the time unit that the piloting ~~means~~ device 19 sends to the valve 13.

Please amend the paragraph beginning at page 7 line 1, as follows:

The piloting ~~means~~ device 19 can be set for piloting a single valve 13, or a plurality of valves 13, if an infusion of a plurality of pharmacological solutions has to be given according to preset times and methods .

Please amend the paragraph beginning at page 7 line 5, as follows:

As, in general, said solutions have to be infused at different times and with different methods, the piloting ~~means~~ device 19 will be programmed to actuate the respective valves 13 according to the times and methods required for the infusion cycle that is to be run.

Please amend the paragraph beginning at page 7 line 10, as follows:

The system according to the invention may be of the disposable type, i.e. be usable for a sole infusion cycle, with one or more pharmacological solutions. In this case the piloting ~~means~~ device 19 is preferably supplied by an electric supply apparatus comprising a battery ~~means~~ 18, inserted into the piloting ~~means~~ device 19. The duration of the battery ~~means~~ 18 will preferably be chosen according to the duration of the infusion cycle to be run.

Please amend the paragraph beginning at page 7 line 17, as follows:

Alternatively, the system according to the invention may be of the multiple use type, i.e. usable for several infusion cycles for the same patient or for several patients. In this case, the piloting ~~means~~ device 19 may be supplied by a rechargeable or replaceable source of supply and may also be connected by means of a suitable connecting ~~means~~ element 17 to a data processing ~~means~~apparatus, by means of which it is possible to modify programming of the microprocessor, to run different infusion cycles for the same patient of for different patients, monitoring the trend of the

infusion cycles, testing new infusion cycles for the purpose of adapting them to the specific physiology of the patient for whom they are intended, etc.

Please amend the paragraph beginning at page 7 line 29, as follows:

The piloting ~~means~~ device 19 can be associated with a reading ~~means~~ device suitable for receiving a data recording support, for example a smart-card, on which data are stored ~~data~~ for programming the microprocessor. In this way programming of the microprocessor may occur both from a remote station and by means of said data recording support.

Please amend the paragraph beginning at page 8 line 1, as follows:

In the case of a multiple use system it is furthermore advantageous to provide a washing ~~means~~ arrangement to eliminate from the fitting ~~means~~ element 12 and from the valve ~~means~~ 13 residue of pharmacological solution, before using the system for the infusion of a new pharmacological solution.

Please amend the paragraph beginning at page 8 line 9, as follows:

Programming can be fixed, for the disposable systems, i.e. intended to run a single cycle or group of infusion cycles on a single patient. Alternatively, programming may be modifiable, if the piloting ~~means~~ device of the system according to the invention is associated with a reading ~~means~~ device for a data-storage support or is connectable to a personal computer.

Please amend the paragraph beginning at page 8 line 17, as follows:

A container 3 containing a preset quantity of pharmacological solution is inserted into the support 4 by connecting the container 3 to the inlet of the valve 13 by means of the fitting ~~means~~ element 12 and the outlet of the valve 13 to a conduit that emerges in a container placed on an electronic balance.

Please amend the paragraph beginning at page 8 line 24, as follows:

Above all, the system according to the invention checks that the new protocol to be stored has not already been stored in the microprocessor of the piloting ~~means~~ device 19, and if it has not an identifier is stored in the microprocessor such as a name of the new infusion protocol, an identifier of the type of pharmacological solution to be used and the maximum quantity in volume of pharmacological solution to be delivered on the basis of the new infusion protocol.

Please amend the paragraph beginning at page 10 line 33, as follows:

Before storing the parameters of the infusion cycle the actual quantity of pharmacological solution delivered by the system may be checked by comparing it with the theoretical quantity that should have been delivered according to the infusion cycle. To that end, the infusion cycle is started and ~~checking~~ one checks at preset time intervals whether or not the ~~cycled~~ cycle has terminated. At the end of the cycle the system ascertains whether the quantity of pharmacological solution provided for by the protocol has been delivered. If the quantity of pharmacological solution (A.U.C) delivered differs from the theoretical quantity to be delivered by a quantity that is greater

than a preset value, for example by more than 10%, an error signal is activated, otherwise the next infusion cycle is started up, if provided for by the protocol. After all the infusion cycles provided for by the protocol have terminated and ~~for each cycle~~ the quantity of pharmacological solution actually delivered has been ascertained for each cycle, the infusion protocol is stored.

Please amend the paragraph beginning at page 11 line 20, as follows:

The protocol can be stored on a personal computer connectable to the system according to the invention, or, if the system according to the invention is provided with a reading ~~means~~ device of a data-storage support, the protocol can be stored on said data-storage support. If the infusion protocol is stored on a personal computer, the latter will transmit to the microprocessor of the command and control ~~means~~ device the data on the infusion cycle, when the system has to run the aforementioned cycle. If, on the other hand, the protocol has been stored on a data-storage support, the transmission to said microprocessor of the data on said protocol is achieved by inserting the data-storage support into the aforementioned reading ~~means~~ device, in such a way that the data can be read by the microprocessor.

Please amend the paragraph beginning at page 12 line 1, as follows:

Lastly, if the system is of the disposable type, the protocol is stored directly in the microprocessor of the piloting ~~means~~ device.